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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,561	10/17/2003	David W. Burke	7404-556	2403

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EXAMINER	
SODERQUIST, ARLEN	
ART UNIT	**PAPER NUMBER**
1743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/688,561	BURKE ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19 and 21* is/are rejected.

7)☒ Claim(s) *18 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2-24-05,8-16-05,2-1-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-17, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over White (US 5,352,351) in view of Singhal, Doss and de Vries. In the patent White teaches a biosensing meter receives a sample strip that includes electrically isolated sense and excitation electrodes bridged by a reaction zone. When a drop of biological sample fluid is placed in the reaction zone, a plurality of fail/safe tests are performed. A drop size test is performed by a circuit that detects the size of the drop placed in the reaction zone. The circuit both detects that a drop has been placed in the reaction zone and further measures a test current level, after a delay, to determine that the drop size is sufficient to enable hydration of reactants in the reaction zone. Subsequently, during the reaction, a "delta" current change is measured at succeeding sample time. This test measures the difference between succeeding current samples during a measurement time. If each succeeding sample is not less than preceding sample by a delta value, a determination is made that the current is not monotonically decreasing and the test is aborted. At the termination of the measurement time, a current sum test is performed wherein a processor calculates a linear sum of all sample test currents and calculates a ratio between that sum and the last current sample. If that ratio matches a pre-calculated constant for the Cottrell relationship, then it is known that the measurement values exhibit the Cottrell relationship. Figure 7 shows the flow chart for this part of the failsafe test. During the time when current values 82, 84, 86, etc. of figure 5 are being measured, a "delta" fail/safe calculation occurs after the second current

measurement and then after each succeeding current measurement (box 120). In essence, it is known that if trace (78, figure 5) follows a Cottrell curve, it monotonically decreases and each succeeding current measurement is less than a preceding current measurement by at least a predetermined delta fail/safe threshold value. That value is obtained from ROM key 48 and is accessed by microprocessor 42. As shown in decision box 120, microprocessor 42 determines that each succeeding sense current i_k is less than or equal to a preceding sampled current value (i_{k-1}) plus the delta fail/safe threshold value. If a succeeding sense current value does not meet that test, an abort message is sent to the user (via display 44) based on the determination that the current waveform is not exhibiting an expected monotonic relationship. This test is repeated for each succeeding current sample, including last current sample 88. Until then, the procedure repeats as shown by decision box 124. Once current measurement 88 has been taken, the procedure moves to a "current sum" fail/safe determination. The current sum fail/safe procedure performs another check on the Cottrell response during the measurement period. When the final current sample is acquired, it is multiplied by two constants (i.e. values) that are accessed by microprocessor 42 from ROM key 48. The results of the multiplication are then used as two limit values against which a sum of all of sensed currents 82, 84, 86 etc. is tested. If the sum falls between the two limits, it is known that trace 78 follows the Cottrell relationship. These actions are illustrated in boxes 122, 124, 126 and 128 in figure 7. Current sum I_{sum} is calculated as shown in box 122 where i_k is one of m current samples. The basis for the current sum fail/safe is the ratio shown in column 8, line 38-44 (expression D). Considering expression (D), it can be concluded that if a trace has Cottrell behavior, then the ratio r shown in equation A calculated with this trace's currents must be equal to $r_{cottrell}$. Inversely, if a trace has non-Cottrell behavior, then the corresponding ratio r from equation (A) is different from $r_{cottrell}$. An allowance is made for some variability and this ratio becomes the test to see if the response is the correct type of response or if the result should be disregarded.

In the paper Singhal teaches a digital approach for the collection and analysis of electrochemical frequency domain spectra is presented for the oxidation of carbohydrates at a copper electrode using a continuous, large-amplitude sine wave as an excitation waveform (AC signal). The background charging current response is a phase-shifted sine wave with the major frequency component concentrated at the fundamental frequency. A nonlinear faradaic response

due to the oxidation of sugars produces significant signal intensities at the higher harmonics as well as the fundamental frequency. Examination of the frequency spectra of glucose and maltose leads to selective and sensitive detection of these sugars at a copper electrode. The selectivity of this measurement relies on the inherent difference in the frequency domain spectra (i.e., magnitude and phase of each harmonic) of sugars of different sizes. This frequency distribution is dramatically affected by temperature, indicating the effect of kinetics in the mechanism for the oxidation of sugars. The sensitivity of the measurement of glucose and maltose is demonstrated with flow injection analysis and post-processing the data with the digital equivalent of a lock-in amplifier. A limit of detection of 8 nM is obtained for glucose when the isolated faradaic current is optimized for phase and frequency. The first page of the article discusses the desire to analyze carbohydrates in biological samples and lists a variety of different known methods. The experimental section describes the apparatus and method used to obtain the results.

In the paper Doss discloses a hyperthermia applicator intended for complete implantation and long-term use. Radio frequency energy is transmitted from an external antenna to a closely coupled subdermal antenna. This internal antenna is connected via a transmission line to deeply implanted electrodes. Changes in temperature at the electrodes result in a change in tissue resistivity which modifies the complex impedance seen at the external antenna terminals. This variation in antenna impedance (magnitude and/or phase angle) can, in principle, be utilized to indirectly monitor and regulate tissue temperature at the electrode location. Test results from conductive-gel tissue phantom experiments are presented.

In the paper de Vries discusses implications of the dielectrical behavior of human blood for continuous online measurement of hematocrit. A study was designed to explore the possibility of detecting the hematocrit of blood by means of admittance measurements. The admittance and phase angle of blood kept in a measuring cell were determined at various frequencies between 60 kHz and 24 MHz. A reliable and accurate estimation of hematocrit was obtained in two ways. First, low-frequency admittance, high-frequency admittance and a factor x, which was the conductive percentage of cell content, were used. Secondly, the maximum phase angle was used. Both methods can be applied to obtain continuous on-line information about hematocrit for blood volume control during hemodialysis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the failsafe procedure of White to incorporate the type of measurements made by Singhal, Doss and de Vries because of the reliability of the measurement of glucose concentration, temperature and hematocrit through the methods of Singhal, Doss and de Vries without providing anything more than the electrodes already present and an AC signal generator/analyzer as shown by Singhal, Doss and de Vries and the ability to determine if a test is usable through the Cottrell ratio as taught by White.

3. Claims 18 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The art of record fails to teach or fairly suggest the method as claimed.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to measuring hematocrit and the differences between admittance and impedance.

5. It is noted that the IDS submitted by applicant has several listed references lined through. Where it is clear that the reference had a date that was not usable, the reference was not submitted by applicant, a foreign reference was not submitted with a translation or explanation as required or the citation was a duplicate, the references have been lined through. If applicant feels that one or more of these references is particularly relevant to the claimed invention, the reference should be listed in an IDS with the relevance clearly noted. It is also noted that around 1/3 of the references were lined through for the above reasons.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Arlen Soderquist
Primary Examiner
Art Unit 1743